




RoughRoad Inc / 28 Mar 2019 / Jean Stahl

IATF 16949:2016 Audit

Complete

Inspection score	Failed items	Created actions
96.44%	0	2
Organization name RoughRoad Inc		
Location 9750 Maloney Rd Brownsburg, IN 46112 United States (39.89797081350416, -86.35255488515223)		
Conducted on 📅 28th Mar, 2019 ⌚ 12:22 PM +08		
Prepared by Jean Stahl		

SafetyCulture Staff created a Medium priority action

ToDo  29th Mar, 2019 8:00 AM +08


New supplier QMS

Hello M, Kindly bring the documents we have related to the new supplier particularly those about their QMS. Thank you.

Verify the organization has a documented supplier selection process and it includes:

8 Operation / 8.4 Control of externally provided processes, products and services

SafetyCulture Staff created a Medium priority action

ToDo  29th Mar, 2019 8:00 AM +08

QMS discussion about new supplier

Hello M, We need to discuss about the new supplier and our QMS. Please meet me tomorrow morning.

4 Context of the organization

92.68%

Introduction

Please complete all sections starting immediately below. This IATF audit checklist will evaluate the organization's compliance with the IATF 16949:2016 standard. Remember to attach evidence to items where required, and to sign off and complete this audit in the final section.

4.1 Understanding the organization and its context

Verify how the organization has determined external and internal issues relevant to its purpose and strategic direction.	Meets requirement
Verify how these issues affect the ability to achieve the intended result of the QMS.	Meets requirement
Verify how the organization monitors and reviews information about these internal and external issues.	Meets requirement

4.2 Understanding the needs and expectations of interested parties

Verify how organization determined relevant interested parties to QMS.	Meets requirement
Verify how the organization has determined the relevant needs and expectations of interested parties.	Meets requirement
Verify how the organization has determined the impact or potential impact of the interested parties.	Meets requirement
Verify how the organization monitors and reviews information about interested parties and their relevant requirements.	Meets requirement

4.3 Determining the scope of the quality management system

Verify the QMS scope considers the following:	Improvement Opportunity
<p>– Notes</p> <p>Improvement opportunity for us because of new supplier.</p>	
<input checked="" type="checkbox"/> External and internal issues.	
<input type="checkbox"/> The requirements of relevant interested parties.	
<input checked="" type="checkbox"/> The products and services of the organization.	
Verify how the organization has determined how the ISO 9001:2015 standard is applied within the organization.	Meets requirement

If the organization has determined any of the requirements of the ISO 9001:2015 standard not to be applicable, show me how conformity of products and services are not affected by this.	Meets requirement
Verify QMS scope is documented.	Meets requirement
Verify scope states what products and services are covered by the QMS and how it justifies instances where requirements cannot be applied.	Meets requirement
Verify support functions included in scope	Meets requirement
If exemption taken, verify that it is for ISO 9001, Section 8.3. Also verify that permitted exclusion does not include manufacturing process design.	Meets requirement
Verify customer-specific requirements evaluated and included in scope	Meets requirement

4.4 Quality management system and its processes

Show me how the processes have been determined and how they interact.	Meets requirement
Verify how the processes for the QMS were determine. Verify the inputs and outputs to the processes.	Meets requirement
Verify the sequence and interaction of of the processes.	Meets requirement
Verify the criteria, methods, measurement and related performance indicators needed to operate and control the processes.	Meets requirement
Verify how resources are determined and allocated.	Meets requirement
Verify how responsibilities and authorities are determined.	Meets requirement
Verify how risks and opportunities are considered and what actions are taken to address them.	Improvement Opportunity
<p>– Notes</p> <p>We have a new supplier and we are yet to have an updated risk assessment. Will meet with M tomorrow to discuss.</p>	
Verify what methods are used to monitor, measure and evaluate processes. Verify changes, if needed, are implemented to achieve intended results.	Improvement Opportunity
Verify how opportunities for improvement for the QMS and its processes are determined.	Meets requirement
Reviewed documented information created to support the operation of its processes.	Meets requirement

Verify conformance to all applicable customer, statutory and regulatory requirements	Meets requirement
Verify documented process	Improvement Opportunity
<p>– Notes</p> <p>Opportunity for us because we are yet to document a new process to integrate the new supplier.</p>	
Where applicable, shall include:	Meets requirement
<input checked="" type="checkbox"/> identification of statutory and regulatory product-safety requirements and customer notification	
<input checked="" type="checkbox"/> special approvals for design FMEA, process FMEAs and control plans	
<input checked="" type="checkbox"/> identification and controls of product safety-related characteristics (including at the point of manufacture)	
<input checked="" type="checkbox"/> reaction plans	
<input checked="" type="checkbox"/> definition of responsibilities, escalation process and flow of information, including top management and customer notification	
<input checked="" type="checkbox"/> training required	
<input checked="" type="checkbox"/> changes of product or process shall be approved prior to implementation	
<input checked="" type="checkbox"/> transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources	
<input checked="" type="checkbox"/> product traceability by manufactured lot (at a minimum) throughout the supply chain	
<input checked="" type="checkbox"/> lessons learned for new product introductions	

5.1 Leadership and commitment

Top management is identified	Meets requirement
Verify top management demonstrates leadership and commitment by:	Meets requirement
<input checked="" type="checkbox"/> Taking accountability for QMS effectiveness	
<input checked="" type="checkbox"/> Ensuring the QMS policy and objectives are established and are compatible with strategic direction and context of organization	
<input checked="" type="checkbox"/> Ensuring the QMS is integrated into organization's business processes	
<input checked="" type="checkbox"/> Promoting the use of the process approach and risk-based thinking	
<input checked="" type="checkbox"/> Ensuring resources are available	
<input checked="" type="checkbox"/> Communicating the importance of effective QMS and of conforming to its requirements	
<input checked="" type="checkbox"/> Ensuring intended outcomes	
<input checked="" type="checkbox"/> Engaging, directing and supporting persons to contribute to the effectiveness of the QMS	
<input checked="" type="checkbox"/> Promoting continuous improvement	
<input checked="" type="checkbox"/> Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility	
Verify how top management demonstrates leadership and commitment with respect to customer focus by ensuring that:	Meets requirement
<input checked="" type="checkbox"/> customer and applicable statutory and regulatory requirements are determined, understood and consistently met.	
<input checked="" type="checkbox"/> the risks and opportunities that affect product and service conformity and the ability to enhance customer satisfaction are determined and addressed.	
<input checked="" type="checkbox"/> the focus of enhancing customer satisfaction is maintained.	
Verify corporate responsibility policies are defined and implemented:	Non-conformance
<p>– Notes</p> <p>There was an issue last month concerning the anonymous reporting system. Will meet M to discuss this whistle blowing policy because we need to set this properly and avoid retaliation from happening to whistle blowers.</p>	
<input checked="" type="checkbox"/> Anti-bribery policy	
<input checked="" type="checkbox"/> Employee code of conduct	
<input type="checkbox"/> Ethics escalation policy ("whistle-blowing policy")	

Verify top management reviews the product realization process for effectiveness and efficiency and is input to Management Review	Meets requirement
Verify top management has identified process owners and that the process owners understand their roles and are competent to perform those roles	Meets requirement

5.2 Policy

Verify the quality policy:	Meets requirement
<input checked="" type="checkbox"/> is appropriate to the purpose and context of the organization and supports its strategic direction.	
<input checked="" type="checkbox"/> provides a framework for setting quality objectives.	
<input checked="" type="checkbox"/> includes a commitment to satisfy applicable requirements.	
<input checked="" type="checkbox"/> includes a commitment to continual improvement of the QMS.	
Verify QMS Policy is maintained as documented information.	Meets requirement
Verify QMS Policy is communicated, understood and applied within the organization.	Meets requirement
Verify QMS Policy is available to relevant interested parties.	Meets requirement

5.3 Organizational roles, responsibilities and authorities

Verify responsibilities and authorities for relevant roles are assigned and communicated within the organization	Meets requirement
Verify top management assigns responsibility and authority for:	Meets requirement
<input checked="" type="checkbox"/> ensuring the QMS conforms to the ISO 9001:2015 and IATF 16949:2016 standards.	
<input checked="" type="checkbox"/> ensuring that processes are delivering their intended outputs.	
<input checked="" type="checkbox"/> reporting on the performance of the QMS and on opportunities for improvement, in particular to top management.	
<input checked="" type="checkbox"/> ensuring the promotion of customer focus throughout the organization.	
<input checked="" type="checkbox"/> ensuring the integrity of the QMS is maintained when changes to the QMS are planned and implemented.	
Verify personnel are assigned responsibility and authority to ensure that customer requirements are met and these assignments are documented.	Meets requirement
Verify personnel responsible for conformity have the authority to stop shipment and stop production to correct quality problems.	Meets requirement

Verify personnel with authority and responsibility for corrective action are promptly informed of products or processes that do not conform	Meets requirement
Verify that personnel across all shifts have responsibility for ensuring conformity to product requirements.	Meets requirement

6.1 Actions to address risks and opportunities

Verify how the internal and external issues and interested parties are considered when planning for the QMS?	Meets requirement
Verify how risks and opportunities are determined and addressed so the QMS can achieve its intended results, prevent and reduce undesired effects and achieve continual improvement	Meets requirement
Verify how actions are planned to address risks and opportunities.	Meets requirement
Verify how actions are integrated and implemented into the QMS processes.	Meets requirement
Verify how the organization evaluates the effectiveness of the actions.	Meets requirement
Verify how actions are taken to address risks and opportunities determined as being appropriate to the potential impact on the conformity of products and services.	Non-conformance
<p>– Notes</p> <p>Will have this taken cared of tomorrow during meeting with M.</p>	
Verify risk analysis includes, at a minimum, lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap and rework.	Meets requirement
Verify retained documented information	Meets requirement
Verify preventive action process	Improvement Opportunity
Verify contingency plans are documented	Meets requirement
Verify contingency plans are prepared for continuity of supply in the event of:	Meets requirement
<input checked="" type="checkbox"/> key equipment failures	
<input checked="" type="checkbox"/> interruption from externally provided products, processes and services	
<input checked="" type="checkbox"/> recurring natural disasters	
<input checked="" type="checkbox"/> fire	
<input checked="" type="checkbox"/> utility interruptions	
<input checked="" type="checkbox"/> labour shortages	
<input checked="" type="checkbox"/> infrastructure disruptions	

Verify validation of manufactured product after re-start	Meets requirement
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6.2 Quality objectives and planning to achieve them

Verify top management ensures that quality objectives are defined, established and maintained at relevant functions, levels and processes.	Meets requirement
Verify the quality objectives are:	Meets requirement
<input checked="" type="checkbox"/> consistent with the quality policy.	
<input checked="" type="checkbox"/> measurable.	
<input checked="" type="checkbox"/> taking into account applicable requirements.	
<input checked="" type="checkbox"/> relevant to the conformity of products and services and to the enhancement of customer satisfaction.	
<input checked="" type="checkbox"/> monitored.	
<input checked="" type="checkbox"/> communicated.	
<input checked="" type="checkbox"/> updated as appropriate.	
Verify objectives are documented.	Meets requirement
Verify how the organization determines what will be done, with what resources, when completed and how the results will be evaluated for quality objectives.	Meets requirement
Verify annual quality objectives and related performance targets (internal and external) are established	Meets requirement

6.3 Planning of changes

Verify how QMS changes are planned systematically.	Meets requirement
Verify how the organization demonstrates the purpose and potential consequences of changes.	Meets requirement
Verify how the organization considers the integrity of the QMS.	Meets requirement
Verify how resources are made available.	Meets requirement
Verify how responsibility and authority is allocated and reallocated.	Meets requirement

7.1 Resources

Verify how resources are determined for the organization.	Meets requirement
Show me how the capabilities and constraints on internal resources are considered.	Meets requirement
Show me how needs from external providers are considered.	Non-conformance
Verify how the organization provides persons necessary to consistently meet customer, applicable statutory and regulatory requirements for the QMS including the necessary processes.	Meets requirement
Verify how the organization determines, provides and maintains the infrastructure for the operation of processes to achieve products and services conformity.	Meets requirement
Verify design layout optimizes material flow, material handling and value-added use of floor space	Meets requirement
Verify assessments of manufacturing feasibility and evaluation of capacity planning as inputs into Management Review	Meets requirement
Verify how the organization determines, provides and maintains the environment for the operation of processes to achieve products and service conformity.	Meets requirement
Verify premises are in a state of order, cleanliness and repair	Non-conformance
<p>– Notes</p> <p>I think we can do better on cleanliness. Will discuss this with M tomorrow. Perhaps reinforcing 5S across the board will solve the cleanliness issue.</p>	
Verify how resources are determined to ensure valid and reliable monitoring and measuring results.	Meets requirement
Verify how the organization ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken and that they are maintained to ensure continued fitness of purpose.	Meets requirement
Verify documented information that shows evidence of fitness for purpose of monitoring and measurement resources.	Meets requirement
Show me how measurement instruments are verified or calibrated at specific intervals against national or international standards. If no standards, show me documented information which is used as the basis for calibration or verification.	Meets requirement
Show me how measurement instruments are identified.	Meets requirement

Show me how measurement instruments are safeguarded from adjustments, damage and deterioration.	Meets requirement
Verify how the organization determines the validity of previous measurements if you find an instrument to be defective during verification or calibration. Verify any actions taken.	Meets requirement
Verify MSA	Meets requirement
Verify criteria used conforms to those in reference manuals on MSA	Meets requirement
Verify documented process for managing calibration/verification records	Meets requirement
Verify calibration/verification activities and records shall include:	Meets requirement
<input checked="" type="checkbox"/> revisions following engineering changes that impact measurement systems	
<input checked="" type="checkbox"/> any out-of-spec readings as received for calibration/verification	
<input checked="" type="checkbox"/> risk assessment caused by out-of-spec condition	
<input checked="" type="checkbox"/> documented information on the validity of previous measurement results when a piece of inspection measurement and test equipment is found to be out of calibration or defective during its planned verification or calibration or during its use	
<input checked="" type="checkbox"/> customer notification if product or material has been shipped	
<input checked="" type="checkbox"/> statements of conformity to spec after calibration/verification	
<input checked="" type="checkbox"/> verification of software version	
<input checked="" type="checkbox"/> records of the calibration and maintenance activities for all gauging, including employee-owned, customer-owned or on-site supplier-owned equipment	
<input checked="" type="checkbox"/> production-related software verification used for product and process control	
Verify defined scope for internal laboratory is documented	Meets requirement
Verify laboratory requirements for:	Meets requirement
<input checked="" type="checkbox"/> adequacy of the laboratory technical procedures	
<input checked="" type="checkbox"/> competency of laboratory personnel	
<input checked="" type="checkbox"/> testing of the product	
<input checked="" type="checkbox"/> traceability to relevant process standard (such as ASTM, EN, etc.) or when no national standard(s) is available, the organization shall define and implement a methodology to verify measurement system capability	
<input checked="" type="checkbox"/> customer requirements, if any	
<input checked="" type="checkbox"/> review of related records	

Verify external laboratories are accredited to ISO/IEC 17025 or national equivalent and or is acceptable to the customer	Meets requirement
Verify scope includes relevant inspection, test or calibration service and the certificate of calibration or test report includes the mark of a national accreditation body	Meets requirement
Verify how the organization determines the necessary knowledge for the operation of processes and achieves conformity of products and services.	Meets requirement
Verify how knowledge is maintained and made available to the extent necessary.	Meets requirement
Verify how the organization determines current knowledge and how its acquires additional knowledge when addressing changing needs and trends.	Meets requirement

7.2 Competence

Show me how you determine the necessary competence of people doing work under your control that affects quality performance.	Meets requirement
Show me how you determine competence on the basis of appropriate education, training or experience.	Meets requirement
Show me how you take actions to acquire necessary competence where applicable and how do you evaluate the effectiveness of those actions.	Meets requirement
Verify documented information as evidence of competence where appropriate.	Meets requirement
Verify documented process(es) for identifying training needs including awareness and achieving competence	Meets requirement
Verify on-the-job training process	Meets requirement
Verify documented process(es) to verify internal and second-party auditors are competent and can demonstrate:	Meets requirement
<input checked="" type="checkbox"/> understanding of the automotive process approach for auditing, including risk-based thinking	
<input checked="" type="checkbox"/> understanding of applicable customer and organization specific requirements	
<input checked="" type="checkbox"/> understanding of applicable ISO 9001 and IATF 16949 requirements	
<input checked="" type="checkbox"/> applicable manufacturing process(es) to be audited, including PFMEA and control plan (second-party auditor only)	
<input checked="" type="checkbox"/> understanding of the applicable core tool requirements	

<input checked="" type="checkbox"/> understanding how to plan, conduct, report and close out audit findings	
Verify how manufacturing process auditors demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (PFMEA) and control plan	Meets requirement
Verify product auditors demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity	Meets requirement
Verify maintenance of and improvement in internal auditor competence by:	Meets requirement
<input checked="" type="checkbox"/> executing minimum number of audits per year, as defined by organization	
<input checked="" type="checkbox"/> maintaining knowledge of relevant requirements based on internal or external changes	

7.3 Awareness

Verify people doing work under the organization's control are aware of:	Meets requirement
<input checked="" type="checkbox"/> the quality policy.	
<input checked="" type="checkbox"/> the relevant quality objectives.	
<input checked="" type="checkbox"/> their contribution to the effectiveness of the QMS, including the benefits of improved performance.	
<input checked="" type="checkbox"/> the implications of not conforming with the QMS requirements.	
Verify that the organization documents process for employee motivation and empowerment:	Meets requirement
<input checked="" type="checkbox"/> to achieve quality objectives	
<input checked="" type="checkbox"/> to make continual improvements	
<input checked="" type="checkbox"/> to create an environment that promotes innovation	
Verify that the organization promotes quality and technological awareness in the whole organization	Meets requirement

7.4 Communication

Verify internal and external communication process (what, when, with whom and how to communicate).	Meets requirement
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7.5 Documented information

Verify documented information required by the ISO 9001:2015 standard.	Meets requirement
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Verify documented information that shows the effectiveness of the QMS.	Meets requirement
Show me that your documented information contains appropriate identification, format (language, software version, graphics, ...) and media (paper, electronic, ...).	Meets requirement
Show me how the documented information is reviewed and approved for suitability and adequacy.	Meets requirement
Show me how you control documented information and make it available and suitable for use. Tell me how you protect your documented information.	Meets requirement
Verify how the organization controls the distribution, access, retrieval, use, storage, preservation, legibility, control of changes, retention and disposition of documented information.	Meets requirement
Verify documented information of external origin is identified, as appropriate, and controlled.	Meets requirement
Verify quality manual and it includes, at a minimum:	Meets requirement
<input checked="" type="checkbox"/> Scope of the QMS, including details of and justification for any exclusions	
<input checked="" type="checkbox"/> documented processes established for the QMS or reference to them	
<input checked="" type="checkbox"/> the organization's processes and their sequence and interactions (inputs and outputs), including type and extent of control of any outsourced processes	
<input checked="" type="checkbox"/> a document indicating where within the QMS their customer-specific requirements are addressed	
Verify record retention policy	Meets requirement
Verify production part approvals, tooling records, product and process design records, purchase orders (if applicable) or contracts and amendments are maintained for the length of time that the product is active for production/service plus one calendar year	Improvement Opportunity
<p>– Notes</p> <p>New supplier's details and paperwork to be included.</p>	
Verify documented process describing the review, distribution and implementation of all customer engineering standards/specifications and related revisions	Meets requirement
Verify records of dates engineering standard/spec change implemented in production (implementation shall include updated documents)	Meets requirement
Verify review is completed within 10 working days of receipt of notification of engineering standards/spec changes	Meets requirement

8.1 Operational planning and control

Verify how the organization has planned, implemented and controlled processes needed to meet the requirements of products and services.	Meets requirement
Verify how requirements for products and services are determined.	Meets requirement
Verify how criteria for processes and acceptance for products and services are determined.	Meets requirement
Verify how resources are determined.	Meets requirement
Verify how process control is implemented.	Meets requirement
Show me documented information that demonstrates processes have been carried out as planned and can demonstrate conformity of products and services.	Meets requirement
Determine how output from the planning process is suitable for operations.	Meets requirement
Verify how planned changes are controlled. Verify how unintended changes are reviewed and what actions are taken to mitigate any adverse effects, as necessary.	Meets requirement
Verify how outsourced processes are controlled.	Meets requirement
Verify topics shall be included in planning for product realization:	Meets requirement
<input checked="" type="checkbox"/> customer product requirements and technical specifications	
<input checked="" type="checkbox"/> logistics requirements	
<input checked="" type="checkbox"/> manufacturing feasibility	
<input checked="" type="checkbox"/> project planning	
<input checked="" type="checkbox"/> acceptance criteria	
Verify organization ensures confidentiality	Meets requirement

8.2 Determination of requirements for products and services

Verify processes created for communicating with customers on information relating to products, services, enquiries, contracts, order handling, customer views, perceptions and complaints, handling or treatment of customer property and specific requirements for contingency actions.	Meets requirement
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Verify process to determine the requirements for products and services to be offered to potential customers and how the process is established, implemented and maintained.	Meets requirement
Verify how product and service requirements including statutory and regulatory requirements are defined. Verify that the organization has the ability to meet the defined requirements and substantiate any claims for its products and services.	Meets requirement
Verify how the organization reviews:	Meets requirement
<input checked="" type="checkbox"/> customer requirements for delivery and post-delivery.	
<input checked="" type="checkbox"/> requirements necessary for customer's specified or intended use, where known.	
<input checked="" type="checkbox"/> statutory and regulatory requirements applicable to the products and services.	
<input checked="" type="checkbox"/> other contract or order requirements.	
Verify retained documented evidence of customer-authorized waiver of above requirements for a formal review	Meets requirement
Verify organization's manufacturing processes are capable (capability analysis, Cp, Cpk, Pp, Ppk)	Meets requirement
Show me that the review is conducted prior to the organization's commitment to supply products and services to the customer.	Meets requirement
Verify how the organization resolves differences in the contract or order requirements from those previously defined.	Meets requirement
Verify how the organization confirms customer requirements where the customer doesn't provide a documented statement.	Meets requirement
Verify documented information of reviews describing new or changed requirements to products and services.	Meets requirement
Verify documented information of amended reviews and how relevant personnel are made aware of those changes.	Meets requirement
Verify written or verbal communication is in language agreed to with the customer	Meets requirement

8.3 Design and development of products and services

Verify how the design and development process is established, implemented and maintained.	Meets requirement
Verify product and manufacturing design is focused on error prevention rather than detection	Meets requirement

Verify that the organization documents the design and development process	Meets requirement
In determining the stages and control for design and development, verify the organization considers:	Meets requirement
<input checked="" type="checkbox"/> the nature, duration and complexity of the activities.	
<input checked="" type="checkbox"/> the requirements that specify particular process stages including applicable reviews.	
<input checked="" type="checkbox"/> required verification and validation.	
<input checked="" type="checkbox"/> responsibilities and authorities.	
<input checked="" type="checkbox"/> how interfaces are controlled between individuals and parties.	
<input checked="" type="checkbox"/> the need for involvement of customer and user groups.	
Verify documented information that confirms design and development requirements have been met.	Meets requirement
Verify design and development planning includes a multidisciplinary approach of all affected stakeholders within its organization and its supply chain (as appropriate).	Meets requirement
Verify product design personnel are competent to achieve design requirements and are skilled in applicable product design tools and techniques.	Meets requirement
Verify process for quality assurance for their products with internally developed embedded software.	Meets requirement
In determining requirements essential for the type of products and services being designed and developed, the organization shall consider:	Meets requirement
<input checked="" type="checkbox"/> functional and performance requirements.	
<input checked="" type="checkbox"/> information derived from previous similar design and development activities.	
<input checked="" type="checkbox"/> statutory and regulatory requirements.	
<input checked="" type="checkbox"/> standard or codes of practice that the organization has committed to implement.	
<input checked="" type="checkbox"/> potential consequences of failure due to the nature of the products and services.	
Verify that the inputs are complete and unambiguous.	Meets requirement
Verify documented information on design and development inputs are retained.	Meets requirement

Verify design input requirements as a result of contract review:	Meets requirement
<input checked="" type="checkbox"/> product specs including but not limited to special characteristics	
<input checked="" type="checkbox"/> boundary and interface requirements	
<input checked="" type="checkbox"/> identification, traceability and packaging	
<input checked="" type="checkbox"/> consideration of design alternatives	
<input checked="" type="checkbox"/> assessment of risks with the input requirements and the organization's ability to mitigate/manage the risks, including from the feasibility analysis	
<input checked="" type="checkbox"/> targets for conformity to product requirements	
<input checked="" type="checkbox"/> applicable statutory and regulatory requirements	
<input checked="" type="checkbox"/> embedded software requirements	
Verify manufacturing process design inputs include (but not limited to):	Meets requirement
<input checked="" type="checkbox"/> product design output data including special characteristics	
<input checked="" type="checkbox"/> targets for productivity, process capability, timing and cost	
<input checked="" type="checkbox"/> manufacturing technology alternatives	
<input checked="" type="checkbox"/> customer requirements	
<input checked="" type="checkbox"/> experience from previous developments	
<input checked="" type="checkbox"/> new materials	
<input checked="" type="checkbox"/> product handling and ergonomic requirements	
<input checked="" type="checkbox"/> design for manufacturing and design for assembly	
Verify error-proofing included in manufacturing process design as appropriate	Meets requirement
Verify multi-disciplinary approach to identify special characteristics:	Meets requirement
<input checked="" type="checkbox"/> documentation of all special characteristics in the drawings, risk analysis (FMEA), control plans and standard work/instructions	
<input checked="" type="checkbox"/> verify special characteristics are identified with specific markings and are cascaded through each of the documents	
<input checked="" type="checkbox"/> development of control and monitoring strategies	
<input checked="" type="checkbox"/> customer-specified approvals	

compliance with customer-specified definitions and symbols (can be organization's equivalent as defined by conversion table)

Verify the organization includes all products and services that affect customer requirements such as sub- assembly, sequencing, sorting, rework, and calibration services in the scope of their definition of externally provided products, processes, and services	Meets requirement
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Verify the organization applies controls to the design and development process to ensure that:	Meets requirement
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the results to be achieved are defined.

reviews are conducted to evaluate the ability of the results of design and development to meet requirements.

verification activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use.

validation activities are conducted to ensure that the resulting products and services meet the requirements of the specified application or intended use.

any necessary actions are taken on problems determined during the reviews, or verification and validation activities.

Verify documented information of these activities are retained.	Meets requirement
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Verify measurement results summary are an input to management review	Meets requirement
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Verify measurements are reported to customer, if required	Meets requirement
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Verify validation performed in accordance to customer requirements, including industry and government regulation standards.	Meets requirement
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Verify interaction of organization's product, including embedded software, within the system of the final customer's product (if contractually agreed with customer)	Meets requirement
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Verify prototype program and control plan (if required)	Meets requirement
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Verify prototype performance testing is monitored for timely completion	Meets requirement
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Verify product and manufacturing approval process conforming to customer requirements	Meets requirement
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Verify approval of external provided parts and services prior to submission of part approval to customer	Meets requirement
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Verify product approval is documented prior to shipment (if required) and retained.	Meets requirement
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Verify the organization ensures the design and development outputs:	Meets requirement
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<input checked="" type="checkbox"/> meet the input requirements.	
<input checked="" type="checkbox"/> are adequate for the subsequent processes for the provision of products and services.	
<input checked="" type="checkbox"/> include or reference monitoring and measuring requirements, as appropriate , and acceptance criteria.	
<input checked="" type="checkbox"/> specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.	
<input checked="" type="checkbox"/> design risk analysis (FMEA)	
<input checked="" type="checkbox"/> reliability study results	
<input checked="" type="checkbox"/> product special characteristics	
<input checked="" type="checkbox"/> results of product design error-proofing, such as DFSS, DFMA and FTA	
<input checked="" type="checkbox"/> product definition including 3D models, technical data packages, product manufacturing information and geometric dimensioning & tolerancing (GD&T)	
<input checked="" type="checkbox"/> product design review results	
<input checked="" type="checkbox"/> service diagnostic guidelines and repair and serviceability instructions	
<input checked="" type="checkbox"/> service part requirements	
<input checked="" type="checkbox"/> packaging and labeling requirements for shipping	
Verify documented information on design and development outputs are retained.	Meets requirement
Verify manufacturing process design output is documented	Meets requirement
Verify manufacturing process design output versus input	Meets requirement
Verify manufacturing process design output includes:	Meets requirement
<input checked="" type="checkbox"/> specifications and drawings	
<input checked="" type="checkbox"/> special characteristics for product and manufacturing process	
<input checked="" type="checkbox"/> identification of process input variables that impact characteristics	
<input checked="" type="checkbox"/> tooling and equipment for production and control, including capability studies of equipment and process(es)	
<input checked="" type="checkbox"/> manufacturing process flow charts/layout, including linkage of product, process and tooling	
<input checked="" type="checkbox"/> capacity analysis	
<input checked="" type="checkbox"/> manufacturing process FMEA	
<input checked="" type="checkbox"/> maintenance plans and instructions	

<input checked="" type="checkbox"/> control plan
<input checked="" type="checkbox"/> standard work and work instructions
<input checked="" type="checkbox"/> process approval acceptance criteria
<input checked="" type="checkbox"/> data for quality, reliability, maintainability and measurability
<input checked="" type="checkbox"/> results of error-proofing identification and verification, as appropriate
<input checked="" type="checkbox"/> methods of rapid detection, feedback and correction of product/manufacturing process nonconformities

Verify the organization identifies, reviews and controls changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.	Meets requirement
Verify documented information on design and development changes, the result of reviews, the authorization of changes and the actions taken to prevent adverse impacts are retained.	Meets requirement
Verify organization evaluates design changes after initial product approval	Meets requirement
Verify documented approval or waiver from the customer prior to production implementation (if required)	Meets requirement
Verify revision level of embedded software and hardware	Meets requirement

8.4 Control of externally provided processes, products and services

1 Action

Verify the organization has a documented supplier selection process and it includes:	Non-conformance
<p>– Actions</p> <hr/> <p>ToDo New supplier QMS</p> <ul style="list-style-type: none"> <input type="checkbox"/> an assessment of the selected supplier's risk to product conformity and uninterrupted supply of the organization's product to their customers <input type="checkbox"/> relevant quality and delivery performance <input type="checkbox"/> an evaluation of the supplier's QMS <input type="checkbox"/> multidisciplinary decision making <input type="checkbox"/> an assessment of software development capabilities (if applicable) 	
Verify "Directed-Buy" external providers meet all requirement	Meets requirement

Verify how the organization ensures externally provided processes, products and services conform to specified requirements.	Meets requirement
Verify controls applied to externally provided processes, products and services when products and services are intended for incorporation into the organization's own products and services, products and services are provided directly to the customer or a process, or part of a process, is provided by an external provider as a result of a decision by the organization.	Meets requirement
Verify how the organization determines and applies criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers.	Meets requirement
Verify documented information of activities and actions arising from the evaluations.	Meets requirement
Verify how the organization determines controls applied to the external provision of processes, products and services and the resulting output.	Meets requirement
Verify how the organization considers the potential impact of the external provided processes, products and services on its ability to meet customer and applicable statutory and regulatory requirements.	Meets requirement
Verify the effectiveness of the controls applied by the external provider.	Meets requirement
Verify how the organization determines the verification, or other activities, necessary to ensure the externally provided processes, products and services meet requirements.	Meets requirement
Verify the organization has a documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity (shall include criteria and actions to escalate or reduce controls based on supplier performance and assessment of product, material or service risk	Meets requirement
Verify the organization has a documented process that purchased products, processes and services conform to the current applicable statutory and regulatory requirements	Meets requirement
Verify the organization ensures special controls defined by the customer are implemented and maintained, including at suppliers	Meets requirement
Verify supplier's QMS is certified to ISO 9001 with the ultimate objective of becoming certified to IATF 16949	Non-conformance
<p>– Notes</p> <p>Will verify this tomorrow during the meeting. Until then, tagging this as nonconformance.</p>	

Verify process for software quality assurance for suppliers of automotive product-related software or automotive products with embedded software	Meets requirement
Verify organization has documented process and criteria to evaluate supplier performance	Meets requirement
Verify organization monitors the following supplier performance indicators:	Meets requirement
<input checked="" type="checkbox"/> delivered product conformity to requirements	
<input checked="" type="checkbox"/> customer disruptions at the receiving plant, including yard holds and stop ships	
<input checked="" type="checkbox"/> delivery schedule performance	
<input checked="" type="checkbox"/> number of occurrences of premium freight	
<input checked="" type="checkbox"/> special status customer notifications related to quality or delivery issues (if provided by customer)	
<input checked="" type="checkbox"/> dealer returns, warranty, field actions and recalls (if provided by customer)	
Verify the organization has documented the criteria for determining the need, type, frequency and scope of second-party audit	Meets requirement
Verify second-party audit reports are retained	Meets requirement
Verify inputs to supplier development includes:	Non-conformance
<input type="checkbox"/> performance issues	
<input type="checkbox"/> second-party audit findings	
<input type="checkbox"/> third-part quality management system certification status	
<input type="checkbox"/> risk analysis	
Verify the organization communicates to external providers its requirements for:	Meets requirement
<input checked="" type="checkbox"/> the processes, products and services to be provided.	
<input checked="" type="checkbox"/> the approval of product and services; methods, processes and equipment; and the release of products and services.	
<input checked="" type="checkbox"/> competence, including any required qualification of persons.	
<input checked="" type="checkbox"/> the external providers' interactions with the organization.	
<input checked="" type="checkbox"/> control and monitoring of the external providers' performance to be applied by the organization.	
<input checked="" type="checkbox"/> verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.	

Verify all applicable statutory and regulatory requirements and special product and process characteristics are passed down to suppliers

Meets requirement

8.5 Production and service provision

Verify the organization has documented information that defines the characteristics of the products to be produced, the services to be provided or the activities to be performed and the results to be achieved.

Meets requirement

Verify the availability and use of suitable monitoring and measuring resources.

Meets requirement

Verify the implementation of monitoring and measuring activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met.

Meets requirement

Verify the use of suitable infrastructure and environment for the operation of processes.

Meets requirement

Verify the appointment of competent persons, including any required qualification.

Meets requirement

Verify the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement.

Meets requirement

Verify the implementation of actions to prevent human error (i.e. poke yoke, visual locations, checklist, emergency stops, templates, document control, ...)

Meets requirement

Verify the implementation of release, delivery and post-delivery activities.

Meets requirement

Verify control plans (in accordance with Annex A) include:

Meets requirement

controls used for the manufacturing process control, including verification of job set-ups

first-off/last-off part validation (as applicable)

methods for monitoring of control exercised over special characteristics defined by both the customer and the organization

the customer-required information (if any)

specified reaction plan (see Annex A)

Verify the control plans shall be reviewed and updated:

Meets requirement

if the organization determines it has shipped nonconforming product to the customer

<input checked="" type="checkbox"/> when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes or risk analysis (FMEA) (see Annex A)	
<input checked="" type="checkbox"/> after a customer complaint and implementation of the associated corrective action (as applicable)	
<input checked="" type="checkbox"/> at a set frequency based on a risk analysis	
Verify if the customer requires approval of Control Plan after review or revision	Meets requirement
Verify standardized work documents are:	Meets requirement
<input checked="" type="checkbox"/> communicated to and understood by the employees who are responsible for performing the work	
<input checked="" type="checkbox"/> legible	
<input checked="" type="checkbox"/> presented in language(s) understood by personnel who follow them	
<input checked="" type="checkbox"/> accessible for use at the designated work area(s)	
Verify standardized work documents include rules for operator safety	Meets requirement
Verify organization verifies job setups	Meets requirement
Verify documentation is maintained for set-up personnel	Meets requirement
Verify organization uses statistical methods of verification, where applicable	Meets requirement
Verify first-off/last-off part validation	Meets requirement
Verify records are retained for process and product approval following set-up and first-off/last-off validations	Meets requirement
Verify organization ensure compliance with requirements after a planned or unplanned production shutdown period	Meets requirement
Verify total productive maintenance system is documented and includes:	Meets requirement
<input checked="" type="checkbox"/> identification of process equipment	
<input checked="" type="checkbox"/> availability of replacement parts	
<input checked="" type="checkbox"/> provision of resource for machine, equipment and facility maintenance	
<input checked="" type="checkbox"/> packaging and preservation of equipment, tooling and gauging	
<input checked="" type="checkbox"/> applicable customer-specific requirements	
<input checked="" type="checkbox"/> documented maintenance objectives (i.e. OEE, MTBF, MTTR and preventive maintenance compliance metrics)	

<input checked="" type="checkbox"/> regular review of maintenance plan and objectives and documented action plan to address corrective actions where objectives are not met	
<input checked="" type="checkbox"/> use of preventive maintenance methods	
<input checked="" type="checkbox"/> use of predictive maintenance methods (as applicable)	
<input checked="" type="checkbox"/> periodic overhaul	
Verify production tooling management system (customer-owned or organization-owned) includes:	Meets requirement
<input checked="" type="checkbox"/> maintenance and repair facilities and personnel	
<input checked="" type="checkbox"/> storage and recovery	
<input checked="" type="checkbox"/> set-up	
<input checked="" type="checkbox"/> tool-change programs for perishable tools	
<input checked="" type="checkbox"/> tool design modification documentation, including engineering change level of the product	
<input checked="" type="checkbox"/> tool modification and revision to documentation	
<input checked="" type="checkbox"/> tool identification, such as serial or asset number; the status, such as production, repair or disposal; ownership; and location	
Verify customer-owned tools and equipment are permanently marked in a visible location	Meets requirement
Verify system implemented to monitors these activities	Meets requirement
Verify production is scheduled to meet customer orders/demands such as JIT	Meets requirement
Verify production scheduling is supported by an information system	Meets requirement
Verify how organization identifies outputs from the process to ensure conformity.	Meets requirement
How does the organization identify the status of process outputs.	Meets requirement
Verify how the organization controls the unique identification of process outputs when traceability is required. Verify documented information of traceability, where required.	Meets requirement
Verify traceability plans:	Meets requirement
<input checked="" type="checkbox"/> enable the organization to identify nonconforming and/or suspect product	
<input checked="" type="checkbox"/> enable the organization to segregate nonconforming and/or suspect product	

<input checked="" type="checkbox"/> ensure the ability to meet the customer and/or regulatory response time requirements
<input checked="" type="checkbox"/> ensure documented information is retained in the format (electronic, hardcopy, archive) that enables the organization to meet the response time requirements
<input checked="" type="checkbox"/> ensure serialized identification of individual products, if specified by the customer or regulatory standards
<input checked="" type="checkbox"/> ensure the identification and traceability requirements are extended to externally provided products with safety/regulatory characteristics

What care is provided to customers' or external providers' property?	Meets requirement
Verify how the organization identifies, verifies, protects and safeguards customers' or external providers' property which is provided for use or incorporation into the organization's products or services.	Meets requirement
Verify retained documented information for property that is damaged or otherwise found to be unsuitable for use.	Meets requirement

Verify how the organization ensures preservation of the process outputs to ensure conformity to requirements.	Meets requirement
Verify organization assesses product in stock, the place/type of storage container and the storage environment at planned intervals	Meets requirement
Verify organization uses inventory management system to optimize inventory turns over time and ensure stock rotation (i.e. FIFO)	Meets requirement
Verify obsolete product is controlled similar to that of nonconforming product	Meets requirement
Verify organization complies with customer requirements for preservation, packaging, shipping and labeling	Meets requirement

Verify the organization considers the following to meet post-delivery activities:	Meets requirement
<input checked="" type="checkbox"/> statutory and regulatory requirements	
<input checked="" type="checkbox"/> potential undesired consequences associated with its products and services	
<input checked="" type="checkbox"/> the nature, use and intended lifetime of its products and services	
<input checked="" type="checkbox"/> customer requirements	
<input checked="" type="checkbox"/> customer feedback	

Verify organization has process for communication of information on service concerns to manufacturing, material handling, logistics, engineering and design	Meets requirement
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Verify the following if a service agreement with the customer exists:	Meets requirement
<input checked="" type="checkbox"/> relevant service centers comply with applicable requirements	
<input checked="" type="checkbox"/> effectiveness of any special purpose tools or measurement equipment	
<input checked="" type="checkbox"/> service personnel are trained in applicable requirements	
Verify how the organization reviews and controls changes for production or service provision.	Meets requirement
Verify retained documented information describing the results of the review of changes, the person(s) authorizing the change and any necessary actions arising from the review.	Meets requirement
Verify documented process	Meets requirement
Verify that the organization:	Meets requirement
<input checked="" type="checkbox"/> defines verification and validation activities	
<input checked="" type="checkbox"/> validates changes before implementation	
<input checked="" type="checkbox"/> documents evidence of related risk analysis	
<input checked="" type="checkbox"/> retains records of verification and validation	
<input checked="" type="checkbox"/> notifies the customer of any planned product realization changes after the most recent product approval (if required)	
<input checked="" type="checkbox"/> obtains documented approval, prior to implementation of the change (if required)	
<input checked="" type="checkbox"/> completes additional verification or identification requirements, such as production trial run and new product validation (if required)	
Verify production trial run for verification of changes made a supplier	Meets requirement
Verify organization has a list of primary and approved back-up/alternate process controls	Meets requirement
Verify alternate method is documented	Meets requirement
Verify alternate control method is approved internally prior to production implementation and by the customer (if required)	Meets requirement
Verify alternative control methods are identified in the Control Plan and are reviewed periodically	Meets requirement
Verify standard work instructions are created for alternative control methods	Meets requirement

Verify alternative process controls are reviewed on a daily basis (at a minimum)	Meets requirement
Verify restart verification is documented for a defined period	Meets requirement
Verify traceability of all product produced with alternative process control devices or processes	Meets requirement

8.6 Release of products and services

Verify at appropriate stages product and service requirements have been met.	Meets requirement
Verify products and services are not released to the customer until the planned arrangements have been satisfactorily completed, unless otherwise approved by relevant authority and, as applicable, by the customer.	Meets requirement
Verify retained documented information that shows evidence of conformity with acceptance criteria and traceability to person(s) authorizing the release.	Meets requirement
Verify verification of product and service requirements are documented as specified in the Control Plan	Meets requirement
Verify a layout inspection and functional inspection is performed per the Control Plan and are available for customer review	Meets requirement
For appearance items, verify the organizations provides:	Meets requirement
<input checked="" type="checkbox"/> appropriate resources, including lighting, for evaluation	
<input checked="" type="checkbox"/> masters for color, grain, gloss, metallic brilliance, texture, distinctness of image (DOI) and haptic technology, as appropriate	
<input checked="" type="checkbox"/> maintenance and control of appearance masters and evaluation equipment	
<input checked="" type="checkbox"/> verification that personnel making appearance evaluations are competent and qualified	
For externally provided processes, products, services, verify the organization utilizes one or more of the following methods:	Improvement Opportunity
<input checked="" type="checkbox"/> receipt and evaluation of statistical data	
<input checked="" type="checkbox"/> receiving inspection and/or testing, such as sampling based on performance	
<input type="checkbox"/> second-party or third-party assessments or audits of supplier sites when coupled with records of acceptable delivered product conformance to requirements	
<input checked="" type="checkbox"/> part evaluation by a designated laboratory	
<input checked="" type="checkbox"/> another method agreed with the customer	

Verify organization confirms and is able to provide evidence that externally provided processes, products and services conform to the latest applicable statutory, regulatory and other requirements in the countries where they are manufactured and in the customer-identified countries of destination, if provided	Meets requirement
Verify acceptance criteria defined by organization	Meets requirement

8.7 Control of nonconforming outputs

Verify that outputs that do not conform to requirements are identified and controlled.	Meets requirement
Verify appropriate action is taken for nonconforming products and services (also include after delivery of product or during/after the provision of services):	Meets requirement
<input checked="" type="checkbox"/> Correction	
<input checked="" type="checkbox"/> Segregation, containment, return or suspension of provision of products and services	
<input checked="" type="checkbox"/> Informing the customer	
<input checked="" type="checkbox"/> Obtaining authorization for acceptance under concession	
Verify conformity to the requirements when nonconforming outputs are corrected.	Meets requirement
Verify retained documented information that describes the nonconformity, describes actions taken, describes any concessions obtained and identifies the authority deciding the action in respect of the nonconformity.	Meets requirement
Verify concession or deviation permit approved by customer prior to further processing from what is currently approved	Meets requirement
Verify organization obtains customer authorization prior to further processing for "use as is" and rework dispositions of nonconforming product (including sub-components)	Meets requirement
Verify records are maintained of expiration date and quantity authorized under concession	Meets requirement
Verify material shipped under concession is appropriately identified	Meets requirement
Verify product with unidentified or suspect status is classified and controlled as nonconforming product	Meets requirement
Verify appropriate manufacturing personnel are trained for containment of suspect and nonconforming product	Meets requirement

Verify documented process for rework confirmation	Meets requirement
Verify instructions for disassembly or rework, including re-inspection and traceability requirements	Meets requirement
Verify documented process for repair confirmation	Meets requirement
Verify instructions for disassembly or repair, including re-inspection and traceability requirements	Meets requirement
Verify documented customer authorization for concession for the product to be repaired	Meets requirement
Verify retained documentation on the disposition of rework including quantity, disposition, disposition date and applicable traceability information	Meets requirement
Verify customer is immediately notified if nonconforming product is shipped	Meets requirement
Verify detailed documentation of the event followed initial communication	Meets requirement
Verify documented process for disposition of nonconforming product not subject to rework or repair	Meets requirement
Verify nonconforming product is rendered unusable prior to disposal	Meets requirement

9.1 Monitoring, measurement, analysis and evaluation

Verify the organization has determined what needs to be monitored and measured, the methods to be used, when it will be performed, analyzed and evaluated.	Meets requirement
Verify the organization evaluates the performance and effectiveness of its QMS.	Meets requirement
Review retained appropriate documented information	Meets requirement
Verify the organization performs process studies on all new manufacturing processes to verify process capability	Meets requirement
Verify the organization's adherence to:	Meets requirement
<input checked="" type="checkbox"/> measurement techniques	
<input checked="" type="checkbox"/> sampling plans	
<input checked="" type="checkbox"/> acceptance criteria	
<input checked="" type="checkbox"/> records of actual measurement values and/or test results for variable data	
<input checked="" type="checkbox"/> reaction plans and escalation process when acceptance criterial are not met	
Verify significant process events (i.e. tool change, machine repair) are retained documented information	Meets requirement
Verify reaction plans created for processes that are either not statistically capable or are unstable. Reaction plans shall include containment of product and 100% inspection (as appropriate)	Meets requirement
Verify records of effective dates of process changes	Meets requirement
Verify that organization has determined the appropriate use of statistical tools	Meets requirement
Verify statistical concepts are understood and used by employees involved in the collection, analysis and management of statistical data	Meets requirement
Verify the organization monitors customers' perceptions and satisfaction based on performance indicators that include but not limited to:	Meets requirement
<input checked="" type="checkbox"/> delivered part quality performance	
<input checked="" type="checkbox"/> customer disruptions	

✓ field returns, recalls and warranty (where applicable)	
✓ delivery schedule performance (including incidents of premium freight)	
✓ customer notifications related to quality or delivery issues, including special status	
Verify organization monitors customer portals and customer scorecards (where provided)	Meets requirement
Verify the organization analyzes and evaluates:	Meets requirement
✓ conformity of products and services.	
✓ the degree of customer satisfaction.	
✓ the performance and effectiveness of the QMS.	
✓ if planning has been implemented effectively.	
✓ the effectiveness of actions taken to address risks and opportunities.	
✓ the performance of external providers.	
✓ the need for improvements the the QMS.	
Verify organization compares trends in quality and operational performance with progress toward objectives and leads to improving customer satisfaction	Meets requirement

9.2 Internal audit

Verify internal audit process is documented	Meets requirement
Verify audits are conducted at planned intervals	Meets requirement
Verify organization has established, implemented, and maintains an internal audit program	Meets requirement
Verify the importance of the process, changes affecting the organization and the results of previous audits are considered	Meets requirement
Verify audit criteria and scope are created for each audit	Meets requirement
Auditors are objective and impartial	Meets requirement
Audit results reported to relevant management	Meets requirement
Verify appropriate correction and corrective actions are taken without delay	Meets requirement
Review retained documented information	Meets requirement
Verify QMS processes are audited over three-year calendar period	Meets requirement

Verify manufacturing processes are audited over three-year calendar period	Meets requirement
Verify all shifts are audited	Meets requirement
Verify products are audited using customer-specific required approaches	Meets requirement

9.3 Management review (go through entire standard and add to inputs)

Verify management reviews QMS at least annually	Meets requirement
Verify inputs to management review includes:	Meets requirement
<input checked="" type="checkbox"/> status of actions from previous management reviews	
<input checked="" type="checkbox"/> changes in external and internal issues relevant to the QMS	
<input checked="" type="checkbox"/> customer satisfaction and feedback from relevant interested parties	
<input checked="" type="checkbox"/> the extent to which quality objectives have been met	
<input checked="" type="checkbox"/> process performance and conformity of products and services	
<input checked="" type="checkbox"/> nonconformities and corrective actions	
<input checked="" type="checkbox"/> monitoring and measurement results	
<input checked="" type="checkbox"/> audit results	
<input checked="" type="checkbox"/> effectiveness of the audit program	
<input checked="" type="checkbox"/> the performance of external providers	
<input checked="" type="checkbox"/> adequacy of resources	
<input checked="" type="checkbox"/> effectiveness of actions taken to address risks and opportunities	
<input checked="" type="checkbox"/> opportunities for improvement	
<input checked="" type="checkbox"/> cost of poor quality (cost of internal and external nonconformance)	
<input checked="" type="checkbox"/> measures of process effectiveness	
<input checked="" type="checkbox"/> measures of process efficiency	
<input checked="" type="checkbox"/> product conformity	
<input checked="" type="checkbox"/> assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product	

<input checked="" type="checkbox"/> review of performance against maintenance objectives	
<input checked="" type="checkbox"/> warranty performance (where applicable)	
<input checked="" type="checkbox"/> review of customer scorecards (where applicable)	
<input checked="" type="checkbox"/> identification of potential field failures identified through risk analysis (such as FMEA)	
<input checked="" type="checkbox"/> actual field failures and their impact on safety or the environment	
Verify outputs to management review includes:	Meets requirement
<input checked="" type="checkbox"/> opportunities for improvement	
<input checked="" type="checkbox"/> any need for changes to the QMS	
<input checked="" type="checkbox"/> resource needs	
<input checked="" type="checkbox"/> action plan when customer performance targets are not met	
Verify retained documented information	Meets requirement

10.1 General

Verify the organization determines and selects opportunities for improvement to improve products and services, corrects, prevents or reduces undesired effects and improves the performance and effectiveness of the QMS.	Meets requirement
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10.2 Nonconformity and corrective action

Verify how organization reacts to nonconformity, including complaints, by evaluating how its takes action to control and correct it and how it deals with the consequences.	Meets requirement
Verify how the organization evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere.	Meets requirement
Verify how organization implements necessary actions.	Meets requirement
Verify how organization evaluates the effectiveness of actions taken.	Meets requirement
Verify the organization updates risks and opportunities determined during planning, if necessary.	Meets requirement
Verify any changes made to the QMS, if necessary.	Meets requirement
Verify retained documented information that provides evidence of the nature of the nonconformity and any subsequent actions taken and the results of any corrective actions	Meets requirement
Verify that the organization has documented process for problem solving including:	Meets requirement
<input checked="" type="checkbox"/> defined approaches for various types and scales of problems	
<input checked="" type="checkbox"/> containment, interim actions and related activities necessary for controlling nonconforming outputs	
<input checked="" type="checkbox"/> root cause analysis, methodology used, analysis and results	
<input checked="" type="checkbox"/> implementation of systemic corrective actions, including consideration of the impact on similar processes and products	
<input checked="" type="checkbox"/> verification of the effectiveness of implemented corrective actions	
<input checked="" type="checkbox"/> reviewing and updating appropriate documented information (where necessary)	
Verify documented process to determine the use of appropriate error-proofing methodologies	Meets requirement

Verify details of error-proofing method used is documented in the process risk analysis (PFMEA) and test frequencies documented in the Control Plan	Meets requirement
Verify records of testing of error-proofing devices	Meets requirement
Verify challenge parts are identified, controlled, verified and calibrated (where feasible)	Meets requirement
Verify reaction plans for error-proofing device failures	Meets requirement
Verify warranty management process (if required)	Meets requirement
Verify method for warranty part analysis, including NTF (no trouble found)	Meets requirement
Verify that the organization has performed analysis on customer complaints and field failures (include embedded software)	Meets requirement
Verify problem solving and corrective action initiated	Meets requirement
Verify the organization communicates the results of testing/analysis to the customer and also within the organization	Meets requirement

10.3 Continual improvement

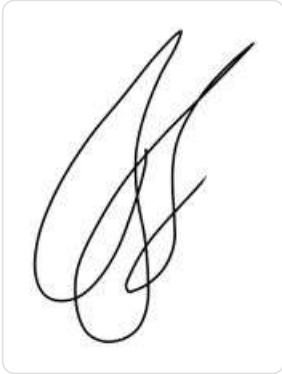
Verify how the organization continually improves. Does it consider the results of analysis and evaluation and the outputs from management review to determine if there are needs or opportunities that shall be addressed as part of continual improvement?	Meets requirement
Verify that the organization's documented process for continual improvement includes:	Meets requirement
<input checked="" type="checkbox"/> identification of methodology used, objectives, measurement, effectiveness and documented information	
<input checked="" type="checkbox"/> a manufacturing process improvement action plan with emphasis on the reduction of process variation and waste	
<input checked="" type="checkbox"/> risk analysis (such as FMEA)	

Sign Off

Sign Off

I, the undersigned, have completed this IATF 16949:2016 audit in an accurate manner. I have attached evidence as required and declare this audit complete.

Full name and signature of auditor



Jean Stahl

28th Mar, 2019 1:31 PM +08